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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,665	06/28/2001	Carlos F. Barbas	8098-005-US-1	2213
32301 7590 06/12/2007 CATALYST LAW GROUP, APC 9710 SCRANTON ROAD, SUITE S-170 SAN DIEGO, CA 92121			EXAMINER CARLSON, KAREN C	
			ART UNIT 1656	PAPER NUMBER
			MAIL DATE 06/12/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/807,665	<b>Applicant(s)</b> BARBAS, CARLOS F.	
	<b>Examiner</b> Karen Cochrane Carlson, Ph.D.	<b>Art Unit</b> 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2006.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Art Unit: 1656

The Office Action is in response to the Appeal Brief filed September 29, 2006.

To re-iterate:

Applicant's election with traverse of Invention 41, SEQ ID NO: 41 in the paper filed March 8, 2004 was acknowledged and searched in the first action on the merits. The traversal was on the ground(s) that Applicants urged that the sequences listed in previously amended Claim 1 are unified by the structure RSDXLV(R/K). It was noted that the amino acid sequence of elected SEQ ID NO: 41 is KSADLKR and does not share this structural sequence. Therefore, the argument that there is a single structure to be searched for all of the sequences listed in previously amended Claim 1 was not considered to be persuasive. The polynucleotide encoding SEQ ID NO: 41 was rejoined because search of the polypeptide resulted in art for the encoding polynucleotide and therefore did not pose an undue burden on the Examiner.

Claims 22-50 have been cancelled. Claim 1 is currently under examination.

Priority is set to **October 16, 1998**.

#### **New Rejections:**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claim 1, it is not clear what is intended by the phrase "...such that the nucleotide binding activity of the polypeptide resides in the nucleotide binding region having the sequence SEQ ID NO: 41...". This phrase can be interpreted in two ways. First, is it intended that only the

Art Unit: 1656

nucleotide binding regions having SEQ ID NO: 41 bind to the nucleotide molecule, and the "nucleotide binding activity" is this binding. Or, second, is it intended that the binding of SEQ ID NO: 41 to the nucleotide molecule can be/must be one of several nucleotide binding regions that bind to the nucleotide molecule, and the activity is transcription resulting from the collective binding of the nucleotide binding regions (in which at least one must be SEQ ID NO: 41). The Examiner has re-read the specification and this phrase does not appear to be found in the specification and therefore the interpretation of the phrase must be clarified.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 1 has been amended to state that SEQ ID NO: 41 binds to nucleotide sequences GAC, GTC, GCT, and GCC. In Figure 1 of the drawings, SEQ ID NO: 41 is shown to bind to nucleotide sequences GAG, GTG, GCT, and GCC. Thus, the inclusion of GAC and GTC is new matter.

Art Unit: 1656

### **Maintenance of Rejections**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claim 1 is again rejected under 35 U.S.C. 102(e) as being anticipated by Barbas et al. (USP 6,242,568, issued June 5, 2001 and having a 102(e) date of December 30, 1996).

Barbas et al. teach C7 zinc finger nucleotide binding polypeptide containing instant SEQ ID NO: 41 (KSADLKR) in Figure 15 and in patent SEQ ID NO: 42 at amino acids 20-26 (Claim 1).

USP 6,140,466 (priority to at least May 27, 1997) is the same up through Example 13 of USP 6,242,568 and would be applied in the same manner as 6,242,568.

This rejection is being maintained because the Examiner has been examining the phrase "...such that the nucleotide binding activity of the polypeptide resides in the nucleotide binding region having the sequence SEQ ID NO: 41..." by the second interpretation, ie, that is it intended that the binding of SEQ ID NO: 41 to the nucleotide molecule must be one of several nucleotide binding regions that bind to the nucleotide molecule, and the activity is transcription resulting from the collective binding of the nucleotide binding regions (in which at least one must be SEQ ID NO: 41).

Applicants' arguments begin on page 6 of the Appeal Brief.

Art Unit: 1656

Applicants again argue that '568 does not teach or suggested an isolated polypeptide that consists essentially of SEQ ID NO: 41. It is not clear why Applicants state this when there are at least 3 regions comprising SEQ ID NO: 41 in the amino acid sequence shown in Figure 15 alone. The phrase "consisting essentially of" is open language, and therefore this rejection stands.

At pages 7-8, Applicants urge that the existence of other nucleotide binding regions in the polypeptide of Figure 15 of Barbas et al. '568 does affect the basic and novel characteristics of the claimed invention because the activity of this polypeptide resides in the specific binding of nucleotide sequences. Rather, Barbas et al. teach that the claimed SEQ ID NO: 41 is a nucleotide binding region that binds triplet GCG (and not GCT, GCC, GAC, or GTG as set forth in Fig 1). Applicants conclude that the zinc finger nucleotide binding polypeptide of Barbas et al. is structurally and functionally different from the claimed zinc finger nucleotide binding polypeptide. The Examiner has reviewed Barbas et al. and does not find the passage that teaches that instant SEQ ID NO: 41 binds to any triplet. Please explain further.

At page 9, Applicants discuss the phrase "consisting essentially of". The Office considers this language to be open. It appears that the new hinge argument manifests itself in what is meant by the phrase "...such that the nucleotide binding activity of the polypeptide resides in the nucleotide binding region having the sequence SEQ ID NO: 41...".

No Claims are allowed.


Art Unit: 1656

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 571-272-0946. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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**KAREN COCHRANE CARLSON, PH.D**  
**PRIMARY EXAMINER**